UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

**MEMORANDUM**

Date: August 8, 2018

Subject: Efficacy Review for EPA File Symbol, 93324-R; CURoxide;
DP Barcode: 446487
E-Sub #: 27167

From: Marcus Rindal, Microbiologist
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)

Thru: Kristen Willis, Acting Team Leader
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)

Kristen Willis

To: Zeno Bain PM 33 / Zebora Johnson
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: Curis System, LLC
1717 Kennedy Point, Suite 1001
Oviedo, FL 32765

FORMULATION FROM LABEL:

| Active Ingredient (s) | % by wt. |
|---|---|
| Hydrogen Peroxide | 7.00 % |
| Other Ingredients | 93.0 % |
| Total | 100.0 % |

## I BACKGROUND

**Product Description (as packaged, as applied):** Ready to Use liquid applied as either a disinfectant spray or fog (via CURIS fogging application equipment only).

**Submission type:** Section 3 product registration

**Requested Action:** With this application the applicant is proposing a microbial disinfectant fogging system consisting of an antimicrobial solution (RTU) and a dedicated fogging apparatus. The liquid may be applied as a ready to use spray disinfectant (bactericide) as well.

**Documents considered in this review:**

- Letter from applicant's representative to EPA dated March 1, 2018
- Data Matrix (EPA Form 8570-35) dated March 1, 2018
- 4 new efficacy studies (MRID No. 50526605 to 50526608)
- Certificates of Analysis
- Proposed label (version not identified)
- Confidential Statement of Formula (EPA Form 8570-4) dated March 1, 2018
- Application for Pesticide Registration (EPA Form 8570-1)
- Certification with Respect to Citation of Data Form (EPA Form 8570-34)
- Formulator's Exemption Statement (EPA Form 8570-27)
- Transmittal document

- Letter from Microchem lab dated August 3, 2018 to address questions from the Agency with regard to monitoring the disinfectant concentration within the chamber throughout the phases of the fogging process (e.g., room charge, contact period, evacuation).

## II AGENCY STANDARDS FOR PROPOSED CLAIMS

The Agency recommends that specific disinfection claims for fogging/misting products and bio-decontamination systems intended for use on hard surfaces be supported by appropriate scientific data demonstrating the efficacy of the product and delivery system against the claimed test organism(s). Testing is accomplished in the laboratory by treating the test organism with the test substance under conditions which simulate as closely as possible the actual conditions under which the test substance is designed to be used. For fogging or misting bio-decontamination devices, disinfectant efficacy evaluations are performed to demonstrate that all exposed hard, non-porous surface within the enclosure are effectively treated with the disinfectant.

NOTE: In the case of the current submission, fogging efficacy was evaluated consistent with a previously approved protocol (Reg. No. 90435PA1). To be considered effective for disinfection the performance standard specified in the protocol is growth of the test organism on 0-1 test carriers per set of ≥ 60 carriers.

The fogging generation system used in the disinfection process will achieve the airborne test material concentration for the time period required for disinfection. The distribution of the fog will be assisted with fans. The system should be a completely self-contained bi-decontamination system with the ability to dehumidify, generate fog, and aerate sealed enclosures. Biological and

chemical indicators will be equally distributed throughout the sealed enclosures to allow verification of treatment efficacy. After treatment, the aeration of the sealed enclosures will be performed until the test material is at an acceptable level. Safety monitoring for active ingredient diffusion into adjacent areas will be conducted during the test and in the sealed enclosure after completion of the disinfection process.

## III PROPOSED DIRECTIONS FOR USE

The proposed label provides the following directions for use:

FOGGING
For use as a microbial disinfectant fogging (micron) (misting) solution for disinfection of all dry, pre-cleaned, hard, non-porous, non-food contact surfaces in spaces and rooms. Do not deviate from standard cleaning protocols when using CURoxide™. Use product only with CURIS® System fogging (misting) equipment following detailed instructions provided in the CURIS® User Manual. Read and follow the directions (in the attached package insert) (on the label) on room preparation, room set-up, treatment procedures, and equipment operating procedures for the specific CURIS® System fogging (misting) machine. This product is for use in CURIS® application equipment only. Read and follow the CURoxide™ (package insert) (label) for complete directions on pre-cleaning, sealing, and use of CURoxide™ in monitored and non-monitored applications. See CURIS® User Manual for operating procedures of the CURIS® System equipment. Do not use this product without development of an appropriate fogging disinfectant plan as described in detail (in the attached package insert) (on the label). Do not deviate from standard cleaning procedures when using CURoxide™ or CURIS® System fogging equipment. CURIS® System micron mist fogging is designed to be the final step in standard cleaning procedures. Not for use as a terminal sterilant or high-level disinfectant for reprocessing of critical or semi-critical medical devices. Protect from radiant heat, freezing and direct sunlight. This product is only for use in the CURIS® System CURIS® fogging equipment, and used in accordance with the CURIS® Fogger Owner's Manual. Read and follow the instructions in the CURIS® Fogger Owner's Manual for directions on pre-cleaning and preparation of a space. See CURIS® Fogger User Manual for operating procedures. Do not use this product without development of an appropriate fogging disinfectant plan as described in the user's manual. Do not deviate from standard cleaning procedures when using CURIS® System. Fogging is designed to be the final step in standard cleaning procedures.

Microbial Disinfection for Fogging
CURoxide™ is a Ready-To-Use product. Do not dilute. Used only on hard, non-porous surfaces. For use as a microbial disinfectant fogging solution for disinfection of dry, pre-cleaned, hard, non-porous, non-food contact surfaces in a space. Do not deviate from standard pre-cleaning protocols when using CURoxide™. Use CURoxide™ only with the CURIS® Fogger following user instructions provided in the CURIS® Fogger User's Manual. Read and follow the directions on room preparation, room set-up, treatment procedures, and equipment operating procedures. Refer to the CURIS® Fogger User's Manual for complete application instructions. For use in sealed rooms or sealed spaces. The CURIS® Fogger should be used when (all room surfaces) (the whole room) needs to be disinfected. Only CURIS® System CURoxide™ products should be used in the CURIS® Fogger. Effective application of CURoxide™ requires adequate product concentration and contact time (FOG and PULSE). The CURIS® Fogger is designed to automatically achieve the correct concentration and contact time of CURoxide™ within a space. Read the CURIS® System CURIS® Fogger Manual prior to initiating the application process to determine the appropriate steps to take in development and application of the process. For use in sealed rooms in Commercial,

Industrial and Institutional settings. The use rate to achieve optimal conditions is approximately .3 mL of product per cubic feet enclosure or room volume using a FOG time that is auto-calculated depending upon the room size. Once initial fogging phase time has elapsed the Contact time (Pulse Phase) must be maintained for a minimum of 30 minutes before room aeration can begin.

Hard Surface Disinfection:
To Disinfect*: To disinfect hard, nonporous surfaces, preclean to remove heavy soils. Hold spray bottle upright 6" to 8" from surface. Spray 2 to 3 seconds until wet. Let stand for 10 minutes. Let air dry.

## IV STUDY SUMMARIES

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 1. | MRID | 50526607 | Study Completion Date: | | | 28FEB2018 | |
| Study Objective | | Disinfectant/ Fogging via Device | | | | | |
| Testing Lab; Lab Study ID | | Microchem Laboratory, Study ID No. GLP1848, Protocol No. P2054 | | | | | |
| Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+ | | *Staphylococcus aureus* (ATCC 6538) | | | | | |
| Test Method | | Evaluating Hard Surface Room Disinfection via a Fogging Device – based on approved protocol | | | | | |
| Application Method | | Liquid applied via fogging device | | | | | |
| Test Substance Preparation | Name/ID | CURoxide / EPA File Symbol 93324-R | | | | | |
| | Lots: ☐ 1 ☐ 2 ☒ 3 | 740717R, 750717R, and 760717R | | | | | |
| | Preparation | Ready-to-use solution, all three lots tested at or below the LCL | | | | | |
| Soil load | | 5% fetal bovine serum | | | | | |
| Carrier type, # per lot | | Glass slide carriers (18mm ×36mm), 60 per lot per contact time | | | | | |
| Test conditions | | Contact time | 20 min fogging + 30 min dwell | Temp | 23±3°C | RH | ≤50% |
| Neutralizer | | Letheen Broth + 0.1% Catalase | | | | | |
| Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.) | | No Protocol Amendments were identified.<br>See Below | | | | | |

The following Protocol Deviation was identified:

On 07 DEC 2017, a deviation from the approved protocol (P2054) occurred during testing of CURoxide (lot: 750717R). The acceptance range for neutralization validation per the protocol was 10-100 CFU to be used for the inoculation of neutralization tubes containing sterile, treated test carriers. The recorded value fell outside this range at 186 CFU. This was thought to have affected the study and therefore the neutralization portion of the study was repeated for CURoxide (lot: 750717R). The neutralization was completed on 12 FEB 2018 by adding 0.5 ml of test substance to carriers, allowing this to rest for the fogging and dwell time (~50 minutes), then neutralizing the carriers by aseptically transferring to neutralization broth tubes. The tubes were then inoculated with an appropriate number of microorganisms (~10-100 CFU).

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 2. | MRID | 50526608 | Study Completion Date: | | | 28FEB2018 | |
| Study Objective | | Disinfectant/ Fogging via Device | | | | | |
| Testing Lab; Lab Study ID | | Microchem Laboratory, Study ID No. GLP1849, Protocol No. P2055 | | | | | |
| Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+ | | *Pseudomonas aeruginosa* (ATCC 15442) | | | | | |
| Test Method | | Evaluating Hard Surface Room Disinfection via a Fogging Device – based on approved protocol | | | | | |
| Application Method | | Liquid applied via fogging device | | | | | |
| Test Substance Preparation | Name/ID | CURoxide / EPA File Symbol 93324-R | | | | | |
| | Lots: ☐ 1 ☐ 2 ☒ 3 | 740717R, 750717R, and 760717R | | | | | |
| | Preparation | Ready-to-use solution, all three lots tested at or below the LCL | | | | | |
| Soil load | | 5% fetal bovine serum | | | | | |
| Carrier type, # per lot | | Glass slide carriers (18mm ×36mm), 60 per lot per contact time | | | | | |
| Test conditions | | Contact time | 20 min fogging + 30 min dwell | Temp | 23±3°C | RH | ≤50% |
| Neutralizer | | Letheen Broth + 0.1% Catalase | | | | | |
| Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.) | | No Protocol Amendments were identified. See Below | | | | | |

The following Protocol Deviations were identified:

1. A deviation from the agreed upon protocol occurred as more than 3 tests (1 test per test substance lot per test microorganism) comprised the study. During a study (GLP1849) conducted with CURoxide (lots: 740717R and 750717R), the results of the study did not meet the success or passing criteria outlined in the approved protocol (P2055), respectively. The presumptive positive results recorded on 08 DEC 2017 were confirmed for 2 of the treated carriers. As a result of the outcome, the fogging time was increased from approximately 17 minutes to 20 minutes and the study was repeated on 05 JAN 2018.
2. On 21 DEC 2017, a deviation from the agreed upon protocol (P2055) occurred. The acceptable range for the mean log density of carrier enumerations was 5.0 - 6.5 corresponding to 1 x $10^5$ CFU/carrier - 3.2 x $10^6$ CFU/carrier, respectively. The enumeration results recorded indicated a mean log density of 4.48 (3.11 x $10^4$ CFU/carrier). As a result of non-compliance with the protocol, CURoxide (lot: 740717R) was repeated on 04 JAN 2018.

| 3. | MRID | 50526605 | Study Completion Date: | 24OCT2017 |
|---|---|---|---|---|
| Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+ | | *Staphylococcus aureus* (ATCC 6538) | | |
| Test Method | | AOAC Germicidal Spray Method | | |
| Application Method | | Sprayed at a distance of 6-8 inches for 4 sprays (on jet setting), at approx. 45° angle (nozzle to carrier) | | |
| Test Substance Preparation | Name/ID | CURoxide / EPA File Symbol 93324-R | | |
| | Lots: ☐ 1 ☐ 2 ☒ 3 | 740717R, 750717R, and 760717R | | |
| | Preparation Details | Ready-to-use solution, all three lots tested at or below the LCL | | |
| Soil load | | N/A | | |
| Carrier type, # per lot | | Glass slides (18×36 mm), 60 per lot | | |
| Test conditions | | Contact time | 10 min | Temp: RT; RH: N/A |
| Testing Lab, Lab Study ID | | Microchem Laboratory, Protocol Number P1928 | | |
| Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.) | | Testing conducted at the LCL. | | |

The following Protocol Amendments were identified:

1. The signed protocol was amended to reflect the following changes: The Study Sponsor company name of CURIS Bio-Decontamination was changed to CURIS Decontamination System. The product name of CURoxide was changed to CURoxide™ for all lots tested per Study Sponsor request. The Study Sponsor name of Steve Grinstead was changed Steve T. Grinstead.
2. The signed protocol was amended to reflect the following changes: The Study Sponsor company name of CURIS Decontamination System was changed to CURIS System, LLC, per the Study Sponsor's request.

The following Protocol Deviation was identified:

1. On 28AUG2017, a deviation to the approved protocol was noted for the soil sterility, PBS sterility and culture diluent sterility for test substance Lot: 740717R. Contamination was observed on the soil sterility, PBS sterility and culture diluent sterility plates, indicating that contamination affected multiple aspects of the study. Additionally, a contaminant was observed in one of the efficacy tubes, and was confirmed to be a contaminant by plating the positive tubes and observing the colony morphology to be different from the viability control. This was thought to affect the outcome of the study, so testing of the product CURoxide™ (Lot: 740717R) was successfully repeated on 28AUG2017.

| 4. | MRID | 50526606 | Study Completion Date: | 19OCT2017 |
|---|---|---|---|---|
| Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+ | | *Pseudomonas aeruginosa* (ATCC 15442) | | |
| Test Method | | AOAC Germicidal Spray Method | | |
| Application Method | | Sprayed at a distance of 6-8 inches for 4 sprays (on jet setting), at approx. 45° angle (nozzle to carrier) | | |
| Test Substance Preparation | Name/ID | CURoxide / EPA File Symbol 93324-R | | |
| | Lots: ☐ 1 ☐ 2 ☒ 3 | 740717R, 750717R, and 760717R | | |
| | Preparation Details | Ready-to-use solution, all three lots tested at or below the LCL | | |
| Soil load | | N/A | | |
| Carrier type, # per lot | | Glass slides (18×36 mm), 60 per lot | | |
| Test conditions | | Contact time | 10 min | Temp: RT; RH: N/A |
| Testing Lab, Lab Study ID | | Microchem Laboratory, Protocol Number P1929 | | |
| Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.) | | No Protocol Deviations were identified.<br>Testing conducted at the LCL. | | |

The following Protocol Amendments were identified: The signed protocol was amended to reflect the following changes: The Study Sponsor company name of CURIS Bio-Decontamination was changed to CURIS Decontamination System. The product name of CURoxide was changed to CURoxide™ for all lots tested per Study Sponsor request. The Study Sponsor name of Steve Grinstead was changed Steve T. Grinstead. The signed protocol was amended to reflect the following changes: The Study Sponsor company name of CURIS Decontamination System was changed to CURIS System, LLC, per the Study Sponsor's request. The signed protocol was amended to reflect the following changes: The Study Sponsor company name of CURIS Decontamination System was changed to CURIS System, LLC, per the Study Sponsor's request.

## V STUDY RESULTS

Room Conditions

| 19DEC2017 – Lot 740717R | | | | | |
|---|---|---|---|---|---|
| Test Organism | Test Substance | Initial Temp/ R.H. | Total Fogging Time | Total Dwell Time | Total Time Evacuation |
| *S. aureus* ATCC 6538 | CURoxide | 22.8°C / 43.4% | 18 min 43 sec | 30 min 0 sec | 122 min 0 sec |

| 5DEC2017 – Lot 750717R | | | | | |
|---|---|---|---|---|---|
| Test Organism | Test Substance | Initial Temp/ R.H. | Total Fogging Time | Total Dwell Time | Total Time Evacuation |
| *S. aureus* ATCC 6538 | CURoxide | 22.0°C / 48.8% | 17 min 5 sec | 30 min 7 sec | 76 min 38 sec |

| 21DEC2017 – Lot 760717R | | | | | |
|---|---|---|---|---|---|
| Test Organism | Test Substance | Initial Temp/ R.H. | Total Fogging Time | Total Dwell Time | Total Time Evacuation |
| *S. aureus* ATCC 6538 | CURoxide | 21.8°C / 37.0% | 20 min 0 sec | 30 min 0 sec | 111 min 23 sec |

Room Conditions

| 04JAN2018 – Lot 740717R | | | | | |
|---|---|---|---|---|---|
| Test Organism | Test Substance | Initial Temp/ R.H. | Total Fogging Time | Total Dwell Time | Total Time Evacuation |
| *P. aeruginosa* ATCC 15442 | CURoxide | 20.3°C / 34.3% | 19 min | 30 min | 107 min |

| 05JAN2018 – Lot 750717R | | | | | |
|---|---|---|---|---|---|
| Test Organism | Test Substance | Initial Temp/ R.H. | Total Fogging Time | Total Dwell Time | Total Time Evacuation |
| *P. aeruginosa* ATCC 15442 | CURoxide | 20.5°C / 39.5% | 19 min | 30 min | 106 min |

| 21DEC2017 – Lot 760717R | | | | | |
|---|---|---|---|---|---|
| Test Organism | Test Substance | Initial Temp/ R.H. | Total Fogging Time | Total Dwell Time | Total Time Evacuation |
| *P. aeruginosa* ATCC 15442 | CURoxide | 21.8°C / 37.0% | 20 min | 30 min | 111 min |

The following activator strip results from each run were provided in the letter from Microchem dated August 3, 2018

Dosage and Activator Strip Results

| GLP Number | Test Organism | Test Date | Lot # Test Substance | Volume Delivered to Room (mL) | Volume of Test Room ($ft^3$) | Dosage ($ml/ft^3$) | Indicator Strop Activated? |
|---|---|---|---|---|---|---|---|
| GLP1848<br>MRID 50526607 | *S. aureus* ATCC 6538 | 19 Dec 2017 | 740717R | 1400 | 3682 | 0.380 | Yes |
| | | 05 Dec 2017 | 750717R | 1410 | 3682 | 0.383 | Yes |
| | | 21 Dec 2017 | 760717R | 1460 | 3682 | 0.397 | Yes |
| GLP1849<br>MRID 50526608 | *P. aeruginosa* ATCC 15442 | 04 Jan 2018 | 740717R | 1450 | 3682 | 0.394 | Yes |
| | | 05 Jan 2018 | 750717R | 1470 | 3682 | 0.399 | Yes |
| | | 21 Dec 2017 | 760717R | 1460 | 3682 | 0.397 | Yes |

FOGGING – Bactericidal Efficacy Results

| MRID | Organism | No. Exhibiting Growth/ Total No. Tested | | |
|---|---|---|---|---|
| | | 740717R | 750717R | 760717R |
| **Contact times (Above) 5% Organic Soil** | | | | |
| 50526607 | *Staphylococcus aureus* (ATCC 6538) | 0[1]/63 | 1[2]/63 | 0/63 |
| | Average $Log_{10}$[CFU/Carrier] | 6.14 | 6.26 | 5.97 |
| 50526608 | *Pseudomonas aeruginosa* (ATCC 15442) | 0/63 | 0/63 | 0[1]/63 |
| | Average $Log_{10}$[CFU/Carrier] | 5.43 | 5.43 | 5.44 |

[1] Two positive carriers showed growth which was determined not to be the test organism based on colony morphology.
[2] One positive carrier showed growth which was determined not to be the test organism based on colony morphology.

GSPT – Bactericidal Efficacy Results

| MRID | Organism | No. Exhibiting Growth/ Total No. Tested | | |
|---|---|---|---|---|
| | | 740717R | 750717R | 760717R |
| **10 min Contact time 5% Organic Soil** | | | | |
| 50526605 | *Staphylococcus aureus* (ATCC 6538) | 0/60 | 0/60 | 1/60 |
| | Average $Log_{10}$[CFU/Carrier] | 6.16 | 6.23 | 6.10 |
| 50526606 | *Pseudomonas aeruginosa* (ATCC 15442) | 0/60 | 0/60 | 0/60 |
| | Average $Log_{10}$[CFU/Carrier] | 5.77 | 5.91 | 5.91 |

## VI STUDY CONCLUSIONS

| MRID | Claim | Surface Type | Application Method(s) and Dilution | Contact Time | Soil load | Diluent | Organism(s) | Data support tested conditions? |
|---|---|---|---|---|---|---|---|---|
| 50526607 | Disinfectant, fogging | Hard, non-porous surfaces | Ready to use liquid applied via fogging device | 30 min | 5% | N/A | • *Staphylococcus aureus* (ATCC 6538) | Yes[1] |
| 50526608 | Disinfectant, fogging | Hard, non-porous surfaces | Ready to use liquid applied via fogging device | 30 min | 5% | N/A | • *Pseudomonas aeruginosa* (ATCC 15442) | Yes[1] |
| 50526605 | Disinfectant, Spray | Hard, non-porous surfaces | Ready to use liquid applied via spray bottle | 10 min | N/A | N/A | • *Staphylococcus aureus* (ATCC 6538) | Yes |
| 50526606 | Disinfectant, Spray | Hard, non-porous surfaces | Ready to use liquid applied via spray bottle | 10 min | N/A | N/A | • *Pseudomonas aeruginosa* (ATCC 15442) | Yes |

[1] When the updated (2018) 810 guidelines go into effect in February of 2018, please note the retesting policy for situations in which there are contaminant microorganisms will also apply for testing to support disinfection by fogging. The protocol should be amended with this in mind.

## VII CONCLUSIONS and LABEL COMMENTS

1. The following proposed label claim **is acceptable** regarding the use of the product, CURoxide (EPA File Symbol 93324-R), as a disinfectant to be applied by fogging via CURIS fogging equipment at a use rate of ~0.3 mL/ft$^3$, with bactericidal activity against the following organisms on hard, non-porous surfaces for a 30-minute contact time:

| | |
|---|---|
| *Staphylococcus aureus* | ATCC 6538 |
| *Pseudomonas aeruginosa* | ATCC 15442 |

These claims **are NOT supported** by the applicant's data. The use directions should be revised to reflect the tested rate which was ~0.4 mL/ft$^3$ in order to make the claim acceptable.

2. The following proposed label claim **is acceptable** regarding the use of the product, CURoxide (EPA File Symbol 93324-R), as a disinfectant to be applied by spray (spray bottle), with bactericidal activity against the following organisms on hard, non-porous surfaces for a 10-minute contact time:

| | |
|---|---|
| *Staphylococcus aureus* | ATCC 6538 |
| *Pseudomonas aeruginosa* | ATCC 15442 |

These claims **are supported** by the applicant's data.

**LABEL COMMENTS**

Please make the following additional label changes:

1. The label and the manual should include the concentration of active ingredient that should be achieved during fogging (e.g. The use rate to achieve a minimum of XXX ppm of hydrogen peroxide is....)
2. The label should include instructions for monitoring in order to achieve the minimum effective concentration as well as monitoring for rentry.
3. The label and manual should specify the product can be used in enclosures up to 105 m$^3$ The name "CURIS® Decontamination System" should be revised throughout both the label and the manual. Per the 810.2100 efficacy testing guidelines, use of the terms decontaminant / decontamination is reserved for products with claims for *Bacillus anthracis*
4. Page 1, above Active Ingredient, the ATCC designation for *Staphylococcus aureus* is incorrectly identified as #6583 and should be corrected to #6538.
5. Page 3,
    a) Remove the following claims:
        (i) "Achieving success in any environment"
        (ii) "Bringing infection prevention into the current century"
        (iii) "Combats resistant pathogens"
        (iv) "Advanced space decontamination"
    b) Revise the following claim to indicate hard, non-porous surfaces
        (i) "all room surfaces"
6. Page 4,
    a) Remove "CURIS Pulse to maintain pathogen kill zone" and "Creating and maintaining healthy spaces" as these statements imply residual activity.

b) Remove "quick" from the claim "....allows for quick room [disinfection] [and] [turnover]...." as claims for fast/quick are limited to contact times of 30 seconds or less
c) Remove "Enhanced Hydrogen Peroxide formula" and "Enhanced formula"
d) Remove "Geobacillus sterathermopholis to validate the fog efficacy"
e) Remove or further clarify "under" in the claim "Kills Under, on top and around surfaces" While the product was tested with inverted carriers, the wording could mislead consumers to think that it is effective on unexposed surfaces (e.g. under something that is set on a counter).
f) Remove "kills [hospital] super bugs"
g) Remove "high elevations, dry climates, humid climates: [-] no problem" No data was submitted to support this claim
h) Revise "Healthcare-grade [Hospital-grade] disinfectant" to "Healthcare [Hospital] disinfectant
i) Remove "kill zone"

7. Page 5,
   a) Remove the following claims:
      i. "Maintaining pathogen [kill zone]"
      ii. "Revolutionary [new] formula"
      iii. "Self-adjusting as needed"
      iv. "Take anywhere disinfection"
      v. "Technology meets [decontamination]"
      vi. "The [only] [most effective] way to eliminate human error from wiping"
      vii. "The most versatile system available"
      viii. "The newest technology in infection prevention"
      ix. "So your loved ones are safer"
   b) Revise all claims indicating "whole room" or "whole space" disinfection to indicate for hard, nonporous surfaces in the room/space.
   c) Remove "decontamination" from the claim "Whole [room] [space] [enclosure] [decontamination] [disinfection]"
8. Page 6,
   a) Remove the following claims:
      i. "Eco-friendly"
      ii. "[Pathogen] Kill Zone [with Pulse Technology]"
      iii. "CURIS® pulse turns on and off to maintain the pathogen kill zone"
   b) Remove "grade" from the claims "CURoxide™ meets EPA standards for healthcare [hospital] grade disinfectant"
   c) Revise "Effectively eliminates [pathogens][bacteria] from hard, non-porous surfaces" to "Effectively eliminates 99.9% of [pathogens][bacteria] from hard, non-porous surfaces"
   d) Clarify "gets everywhere" claims as described in 4(e).
   e) Revise the claim "Great [suitable] for whole [complete] room [disinfecting] [disinfection]" to indicate for hard, nonporous surfaces in the room/space.
9. Page 7,
   a) Remove the following claims:
      i. Micron Mist Better, Smarter, Faster [more effective] then the rest
      ii. Multiple [Multi-faceted] killing mechanism[s]
      iii. Multiple [Multi-faceted] mechanism[s] of killing action

iv. Multiple modes of killing action
v. Pulse helps to maintain [pathogen] kill zone
vi. Reaches in every nook,
vii. Reaches up to 100% of surfaces
viii. Shelf life of 2 years
ix. Turn a room in around an hour
x. Uses 1/3 less chemical
xi. "The [Germ] stops here!"
xii. "Under fog protection"

b) Revise references to, "Kills 99.99999% of ..." to, "Kills 99.9% of ..."

10. Pages 7 and 9, claims to reduce the risk of cross-contamination should include the qualifier, "on treated surfaces" For example, the claim "Reduce[s] risk of cross contamination associated with contaminated surfaces" should be revised to "Reduce[s] risk of cross contamination on treated surfaces" Similarly, the claim "Reduce[s] the risk of cross contamination associated with using a rag, wipe or sponge" should be revised to "Reduce[s] the risk of cross contamination on treated surfaces associated with using a rag, wipe or sponge"
11. Page 8,
    a) Claims "whole" or "complete" room disinfection should be qualified to indicate for hard, nonporous surfaces in the room/space.
    b) Claims for "99.99%" should be revised to "99.9%"
    c) Claims for "eliminates" should be removed or clarified with "99.9%"
12. Page 9,
    a) Claims for "whole" or "complete" room disinfection should be qualified to indicate for hard, nonporous surfaces in the room/space.
    b) Claims for "eliminates" should be removed or clarified with "99.9%"
    c) Remove "grade" from "heathcare-grade"
    d) The "Medical Use Sites" heading should be qualified to indicate "for use on hard, nonporous surfaces"
13. Page 12, revise the directions for use for disinfection to indicate the surface should remain wet for the contact time.
14. Page 14,
    a) Remove the claim "Stop the spread of germs on treated surfaces, spray on animal chew toys". For more information on use of the term germs see the following; https://www.epa.gov/pesticide-labels/use-term-germs-antimicrobial-labels
    b) Remove "decontamination" from the claim "for use in whole space [decontamination][disinfection]
    c) Claims for "whole" or "complete" room disinfection should be qualified to indicate for hard, nonporous surfaces in the room/space.
15. Page 16,
    a) Remove references to the product as "one step," as the product was not tested as a disinfectant with soil to support this claim.
    b) Revise the claim for "99.9999%" to "99.9%"
16. Page 17,
    a) Remove reference to product as "one step," "one-step," "in one step," etc.
    b) References to, "99.99999% of ..." should be amended to, "99.9% of ..."
    c) Remove "germicidal" (see 14(a))
    d) Clarify "gets everywhere" claims as described in 4(e).

e) Claims for "eliminates" should be removed or clarified with "99.9%"
f) Remove all claims for "Tough on germs" (see 14(a))
g) Remove "grade" from the claim "CURoxide™ meets EPA standards for healthcare [hospital] grade disinfectant"

17. Page 18,
    a) Remove reference to, "Homes," under AREAS OF USE INCLUDE:.
    b) References to, "99.99999% of ..." should be amended to, "99.9% of ..."
    c) Claims for "eliminates" should be removed or clarified with "99.9%"
    d) Claims for "whole" or "complete" room disinfection should be qualified to indicate for hard, nonporous surfaces in the room/space
18. Page 19,
    a) The "Medical Use Sites" heading should be qualified to indicate "for use on hard, nonporous surfaces"
19. Page 22, remove the following use surfaces:
    a) Medical Use Surfaces:] Soft Surfaces
    b) Curtains
    c) Bedding
    d) Sofa's
    e) Fabric's
20. Page 24, the heading for "Food Service Use Sites" should specify for non-food contact surfaces
21. Page 25, remove "curtains"
22. Page 27, remove "upholstery"
23. Page 28, remove the following use surfaces:
    a) Car Seat Upholstery
    b) Carpets
    c) Clothes, diaper
    d) Couch(es)
24. Page 29, remove the following use surfaces:
    a) Fabric
    b) Gym bags
    c) Laundry bags
25. Page 30, remove the following use surfaces:
    a) Pillow(s)
26. Page 31,
    a) Remove the following use surfaces:
        i. Upholstery
        ii. Uniforms
        iii. Window treatments
        iv. Bedding (bedspreads)
        v. Back Packs
        vi. Blankets (comforters)
        vii. Draperies
        viii. Duvet Covers
        ix. Stuffed Animals